

UNIFYING MEDICAL & NUTRITIONAL SCIENCES SAM

February 26, 1998

996 53 JUN-5 A9 A125 Food and Drug Administration Office of Special Nutritionals (HFS-450) Center of Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101,93 that DR RX, Inc., Doctor's Nutriceuticals® Brand within the past 30 days commenced sales of a nutritional supplement bearing the following statements on the labeling:

# (SEE SUBSEQUENT PAGES )

I certify that the information contained in this notice is complete and accurate and that DR RX, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Carl J. Koenigsmann, M.D., C.O.O.

975 - 0162

LET 1638

**RELAXTM** 

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® RELAX™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally promote relaxation and help combat the daytime effects of stress and nervousness.

When properly formulated as in this product, standardized Valerian, Kava Kava and Passionflower have now been scientifically documented as having nutritionally promoting calmative and mood regulating properties.

#### CHOLESTEROL SUPPORT™

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® CHOLESTEROL-SUPPORT™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support and promote healthier cholesterol and Homocysteine levels, and help nutritionally support negating excess harmful free radicals.

When properly formulated as in this product, standardized Gugul, and concentrated Garlic extract have now been scientifically documented to help nutritionally support and promote healthier cholesterol levels. Selenium is scientifically documented to nutritionally support natural antioxidants, via its synergistic activity. Folic acid has been scientifically documented to nutritionally promote Homocysteine levels.

#### CARDIAC SUPPORT™

## TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® CARDIAC SUPPORT™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support a healthier heart and cardiovascular system function as well as nutritionally promoting healthier Homocysteine levels.

When properly formulated as in this product, vitamin E is recognized as a potent anti-oxidant or free radical scavenger and can help nutritionally promote decreasing free radical stress on the cardiovascular system. L-Carnitine, standardized Hawthorn Berry Extract, standardized Green Tea extract, Grape Seed Extract and Motherwort are also scientifically documented to nutritionally support and promote the health of the heart. On a cellular level, CoQ10 is an important coenzyme which has also been shown to have an essential role in nutritionally promoting energy production. Folic acid is scientifically documented to help nutritionally promote healthier Homocysteine levels.

### **ENERGIZETM**

## TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® ENERGIZE™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally promote increased energy, endurance, vitality and help combat fatigue.

When properly formulated as in this product, standardized Ginseng and Schizandra are scientifically documented to act as adaptogens, thus nutritionally supporting normalized body functions and help nutritionally support resistance to stress. Guarana is scientifically documented for nutritionally promoting increased energy levels.

#### PROSTATE SUPPORT™

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® PROSTATE SUPPORTTM is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support and promote prostate health and function.

When properly formulated as in this product, Saw Palmetto Berry powdered extract standardized for a minimum of preferred 45-55% Fatty Acids and biologically active Sterols (delivering more preferred fatty acids and biologically active sterols than 320mg of 85-95% oil), as well as standardized Pygeum Africanum, have impressive scientific documentation for nutritionally supporting and promoting prostate health and function. Lycopene, a tomato carotenoid, has been recently scientifically documented to help nutritionally support the long term health of the prostate. Zinc can also nutritionally support prostate health and function.

## GOOD NIGHT'S SLEEPTM

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® GOOD NIGHT'S SLEEPTM is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support and promote a more relaxed and restful sleep.

When properly formulated as in this product, standardized Valerian, Passionflower and Hops have now been scientifically documented to help nutritionally promote restful sleep and relaxation. Melatonin has also been scientifically documented to nutritionally support our natural internal rhythms or biologic clock, responsible for a healthier sleep-wake cycle, and for helping to nutritionally support addressing the effects of jet lag.

### ENHANCED WELL BEINGTM

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® ENHANCED WELL BEINGTM is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support improved overall mood and a sense of well being.

The standardized herb St. John's Wort 0.3% Hypericin is a scientifically documented, most popular European nutritionally support product, now available in the United States for nutritionally supporting loss of well being or feelings of the "blues".

#### ENHANCED MINDTM

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® ENHANCED MIND™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support and promote overall brain enhancement, thus improving memory, concentration and mental sharpness.

When properly formulated as in this product, standardized Ginkgo Biloba as well as Siberian and Panax (Asian) Ginseng have been scientifically documented to help nutritionally support and promote concentration, memory, and brain enhancement.

#### MENOPAUSE SUPPORT™

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® MENOPAUSE SUPPORT™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support addressing the negative effects associated with the change of life.

When properly formulated as in this product, standardized Dong Quai and VItex are now scientifically documented to nutritionally support addressing the negative effects associated with the change of life. Isolated Soy Protein, containing standardized isoflavones, has been scientifically shown to be a natural source of phytoestrogens, Passionflower has also been scientifically shown to help nutritionally promote relaxation thus helping to combat tension and irritability.

### ENHANCED PLEASURETM

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS®ENHANCED PLEASURE™ scientifically formulated with ingredients shown to nutritionally promote the enhancement of sexual performance and thus pleasure. It is a comprehensive broad spectrum product.

When properly formulated as in this product, standardized Yohimbe has now been scientifically documented to nutritionally support the enhancement of sexual performance and thus pleasure; as in Muira Puama and Damiana. Schizandra and ginseng have been scientifically shown to help nutritionally support and promote endurance and stamina. DHEA has also been scientifically documented as a natural hormone building block substance.

#### ANTI-AGING SUPPORT™

# TEXT OF CLAIM(S):

DOCTOR'S NUTRICEUTICALS® ANTI-AGING SUPPORT™ is a comprehensive broad spectrum product, scientifically formulated with ingredients to help nutritionally support addressing excessive (harmful) free radicals, considered in scientific documentation to contribute to the aging process as well as helping to nutritionally support and promote good overall health.

When properly formulated, as in this product, Vitamin C and E are recognized as powerful antioxidants. Vit P (Bioflavanoids) and Selenium act synergistically with these antioxidants and can help further enhance their activity. Antioxidants nutritionally promote deactivating or negating excessive (harmful) free radicals. FoTi and Grape Seed Extract have now also been shown to help nutritionally support connective tissues, which are the supporting structures of the blood vessels, heart and skin. Coenzyme Q10 is a substance found in all cells of the body and has been scientifically shown to nutritionally promote energy production.